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*BY HAND DELIVERY* *May 1, 2000*

Docket No. 98-091-1
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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Re: Proposed Rule; Administrative Practices and Procedures; Good Guidance Practices; Docket No. 99N-4783; 65 Fed. Reg. 7321 (Feb. 14, 2000)

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) welcomes this opportunity to comment on the above-referenced proposed rule. AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 members are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. Its members include many processors who often rely upon the advice and guidance of the Food and Drug Administration in their efforts to ensure compliance with both the letter and the spirit of applicable law and regulations. Accordingly, AFFI and its members have a direct interest in FDA's procedures for preparing and implementing guidance documents.

AFFI recognizes the importance of establishing Good Guidance Practices (GGPs), and generally supports codification of the GGPs. AFFI is concerned, however, that FDA may be unnecessarily detracting from the value of its guidance documents by failing to provide companies in compliance with FDA guidances with a safe harbor from regulatory action. AFFI urges FDA to use its enforcement discretion to provide companies that adhere to FDA guidance documents with a safe harbor that protects them from enforcement action. For example, a company that follows FDA's guidance on the preparation of nutrient databases, and relies upon such databases to place nutrient information on retail packages, should be confident that FDA will not later decide to take enforcement action against the company based on those nutrient declarations.

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Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), although guidance documents are not legally "binding" on FDA, the agency must ensure that its employees do not deviate from such guidances without appropriate justification and supervisory concurrence. [1]/ Moreover, although such documents do not technically create or confer any rights on any person, they are supposed to present the agency's views on matters under FDA's jurisdiction. [2]/ In short, FDAMA provides that a guidance document will represent FDA policy, and that the agency will act in keeping with a guidance document unless the agency can show that there is appropriate justification for deviation.

Although the statute provides FDA with discretion to take enforcement action inconsistent with a guidance document if there is appropriate justification, AFFI recommends that, when faced with a situation in which there may be appropriate justification to deviate from a given guidance document, the agency amend the guidance document itself to indicate the existence of certain limited exceptions and to provide industry with notice and the opportunity to implement necessary changes. If the agency believes that a change in policy is warranted, or believes that the policy is subject to certain limited exceptions, FDA should be able to articulate its new enforcement position and provide industry with notice through modification of the guidance document, rather than through enforcement actions against someone who relied in good faith on FDA's stated interpretation of its current policy.

It is especially important for FDA to promote the utility of informal guidances at a time when the agency may face budget restraints. If a guidance document does not provide a safe harbor for the regulated community, companies will continue to require case-by-case assurances from the agency that they are in compliance – unnecessarily draining already limited resources.

In addition, AFFI encourages FDA's development of an appeals mechanism, as required under FDAMA, [3]/ to address complaints regarding FDA's development and use of guidance documents. However, AFFI believes that the appeals mechanism, without the establishment of a safe harbor, would be insufficient to address concerns with actions taken by FDA that are inconsistent with its guidance documents.

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-/ 21 U.S.C. § 371(h)(1)(A).
-/ 21 U.S.C. § 371(h)(1)(B).
-/ 21 U.S.C. § 371(h)(4).

If FDA takes the position that the guidance documents will not provide a safe harbor, then, at the very least, AFFI believes that compliance with an FDA guidance document should provide evidence of a company's intent to comply with agency regulations in any related enforcement proceeding. In all fairness, if a company adheres to the agency's own interpretation of its requirements, FDA should be willing to recognize the company's attempt at compliance. If guidance documents do not provide even this small amount of certainty, their usefulness to industry is severely limited. It is in the agency's interest to provide this minimal amount of assurance to industry.

AFFI appreciates this opportunity to comment and looks forward to working cooperatively with the agency in this most important area.

Sincerely,

Leslie G. Sarasin, CAE
President and
Chief Executive Officer

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